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Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID-19 Public Health Emergency

Guidance for Industry

May 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number, FDA-2020-D-1139, and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to INFOCenter-CFSAN@fda.hhs.gov to receive an additional copy of the guidance. Please include the docket number, FDA-2020-D-1139, and complete title of the guidance in the request.

Questions

For questions about this document, contact FDA at 1-888-723-3366 or INFOCenter-CFSAN@fda.hhs.gov.

Table of Contents

I. Introduction..... 1
II. Background..... 2
III. Discussion..... 3

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or the Agency) plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide certain FDA-regulated food establishments (i.e., human food facilities and farms, but not restaurants and retail food establishments), with a convenient mechanism to voluntarily report to FDA if they have temporarily ceased or significantly reduced production or if they are considering doing so. This reporting mechanism may also be used to request dialogue with FDA on issues related to continuing or restarting safe food production during the pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and renewed for 90 days on April 21, 2020, effective April 26, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)).

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Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Service (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

The Food and Agriculture Sector is considered critical infrastructure³ because its continued operation is vital to the United States. However, the pandemic is affecting the ability of food establishments to operate. Although closures and reductions in production in the meat industry have received the majority of attention in the press⁴, there have also been press reports⁵ about FDA-regulated food establishments that have temporarily closed or face pandemic-related challenges that could lead to closures.

III. Discussion

Facilities that manufacture/process, pack or hold food for consumption in the United States must

¹ Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

³ <https://www.cisa.gov/food-and-agriculture-sector>.

⁴ <https://www.cnn.com/2020/04/12/business/meat-plant-closures-smithfield/index.html>.

⁵ <https://www.wsj.com/articles/coronavirus-closures-extend-to-packaged-food-production-11587408510>.

Contains Nonbinding Recommendations

register with FDA when initially beginning operation and then update that registration on a biennial basis and within 60 days of when certain changes in their operations occur. (see 21 CFR part 1, subpart H). However, during the pandemic, more rapid and specific notification regarding certain FDA-regulated food establishments that are temporarily closing or reducing production will help FDA to better understand the current status of the food supply and address challenges facing food producers to help support food production. Further, food establishments may wish to request assistance from FDA in addressing pandemic-related challenges.

Therefore, FDA is providing a mechanism for FDA-regulated establishments to voluntarily notify the Agency of temporary closures and significant reductions of production during the pandemic or to request assistance from FDA regarding issues that may affect continuity of operations during the pandemic. FDA can provide information, such as relevant guidance, in areas including protecting worker safety, inability to access protective equipment for personnel, and supply chain imbalances. FDA will work with its federal government partners, such as the Centers for Disease Control and Prevention, Department of Homeland Security, Department of Agriculture, Occupational Safety and Health Administration, the Federal Emergency Management Agency, and State, local, tribal and territorial regulatory partners to provide the most up-to-date information.

Reporting and Requesting Protocol:

1. Establishments that wish to voluntarily report a temporary closure/significant production reduction or request assistance should do so through the FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) Food and Cosmetic Information Center (FCIC). The CFSAN FCIC can be accessed [here](#);
2. Check the box "Is your inquiry specific to Coronavirus" on the FCIC webpage and there will be an option to choose to report a temporary closure or a significant reduction in production due to circumstances associated with COVID-19 and request assistance;
3. Check the box "Report a Temporary Closure/Production Reduction and Request Assistance" which will result in users receiving an email with a link to provide information;
4. Via the email link, complete and submit the form requesting the following information:
 - Whether the establishment is a facility, a farm, or a mixed-type facility;
 - Whether assistance is requested and a brief description of the nature of the request;
 - The name, address, and contact information for the establishment;
 - If applicable, the Food Facility Registration Number and Food Establishment Inventory (FEI) Number, so that FDA can cross reference the notification or request with information in our databases;
 - If applicable, information about when an establishment closed or reduced operations that significantly impact production (or estimates doing so) and an estimate of how long the establishment will likely remain closed or at partial operation;
 - Examples of reduced operations that significantly impact production include operation alterations that reduce production volume by a significant percentage (e.g., reductions of 15% or greater), but not temporary operation changes to accommodate activities like additional cleaning; and
 - The number of employees at the establishment.

FDA will use the information provided to help understand the status of FDA-regulated food

Contains Nonbinding Recommendations

establishments and the food supply in light of circumstances associated with the pandemic. FDA does not intend to use the information to target establishments for inspections as a result of temporary closure or reduced production during the pandemic. Further, we do not expect the risk profile of an establishment to change as a result of a temporary closure. If we learn that an establishment is making permanent changes to its operations, such as making a different type of commodity, we will incorporate that information, which could change the risk profile of a facility, into our future work planning process.

This guidance does not apply to restaurant and retail food establishments; FDA will work with their trade associations and state and local officials to obtain information and provide any appropriate assistance.